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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/659,737	09/11/2000	Miroslav Blumenberg	71369.172 and PFI-024US	5697

7590

01/02/2003

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EXAMINER

MONSHIPOURI, MARYAM

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 01/02/2003

16
Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/659,737

Applicant(s)

Blumenberg et al.

Examiner

Maryam Monshipouri

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1652



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above, claim(s) 6-21, 24, and 26-47 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-5, 22, 23, and 25 is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 10 6) ☐ Other:

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Applicant's response to restriction requirement filed 10/10/2002 (paper # 15) is acknowledged. Applicant elected Group I invention directed to claims 1-5, 22-23 and 25 without traverse. Claims 6-21, 24 and 26-47 are withdrawn as drawn to non-elected invention. are under examination on the merits.

DETAILED ACTION

Claims 1-5, 22-23 and 25 are under examination on the merits.

Claim Objections

1. Claims 22 and 25 are objected to because of the following informalities: claim 22 still depends from non-elected claims 6, 11 and 17. Applicant is advised to delete said claims from claim 22. Similarly, claim 25 still recites non-elected sequences SEQ ID NO:4, 6, 8, 10 and 13. Applicant is advised to delete said sequences from claim 25. Appropriate correction is required.

2.

Double Patenting

3. Claim 5 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 2. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP §

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706.03(k). It is not clear how the scope of claim 5 differs from that of claim 2 as both claimed DNA sequences must comprise SEQ ID NO:1.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 3-4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated DNA molecules that are at least 90% homologous to SEQ ID NO:1 while being capable of encoding products with MLK4 activity, does not reasonably provide enablement for any homologous sequence to SEQ ID NO:1.

The criteria for undue experimentation, summarized in *re Wands*, 8, USPQ2n 1400 (Fed. Cir. 1988) are: 1) the quantity of experimentation necessary, 2) the amount of direction or guidance presented, 3) the presence and absence of working examples, 4) the nature of the invention, 5) the state of prior art, 6) the relative skill of those in the art, 7) the predictability or unpredictability of the art, and 8) the breadth of the claims.

The specification defines the term "homologous" specifically in page 8, in terms of having at least 70% identity to SEQ ID NO:1 with no function. The specification fails to teach which critical residues in claimed sequences should be preserved in order for the homologs to encode products with MLK4 function. No examples of such sequences are provided either. The state of

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prior art indicates that any sequence that has 70% identity to SEQ ID NO:1 is not necessarily going to encode products with MLK4 function.

Therefore due to lack of sufficient guidance and examples provided in the specification and due to unpredictability of prior art as to structural requirements of homologs which are still capable of encoding products with MLK4 function one of skill in the art has to go through the burden of undue experimentation in order to use the invention as broadly claimed.

With respect to claim 4, the term "substantial portion" in claim 4 is defined in page 10 of the specification as a DNA fragment (of at least 45 bases in length) capable of encoding any 15 amino acid fragments of SEQ ID NO:2 with no specific function. Applicant is well aware that 15 amino acids are not sufficient to retain any activity. Thus, sequences that consist of any 45 bases of SEQ ID NO:1 are of broad scope. Many of said sequences may be used as probes to identify many full-length DNA sequences that do not encode products with MLK4 function.

Again, considering the *re Wands* factors above, applicant did not indicate which critical probes of 45 bases in length are likely to hybridize to MLK4 encoding sequences. No examples of such sequences are provided either.

Therefore due to lack of sufficient information and examples provided in the specification and due to unpredictability of prior art as to structural requirements of probes that can mainly hybridize to MLK4 encoding sequences of this invention and exclude most of the others one of skill in the art has to go through the burden of undue experimentation in order to screen for

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probes that are supported by the specification and such claim 4 goes beyond the scope of the disclosure.

6. Claim 3-4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 3-4 as recited are directed to a **genus** of polynucleotide molecules having 70% identity to SEQ ID NO:1 with no function, and a **genus** of DNA sequences consisting of any 45 bases of SEQ ID NO:1 with no function, respectively, which are not adequately described in the specification.

The specification does not contain any disclosure of the function of all DNA sequences that are homologous (i.e having 70% identity) to SEQ ID NO:1. The genus of cDNAs that comprise these above cDNA molecules is a large variable genus with the potentiality of encoding many different proteins. Therefore, many functionally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses only a **single species** of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus.

With respect to claim 4, as mentioned above, 45 bases are insufficient to encode any product of any function. Thus, claimed **genus** of probes is capable of hybridizing with many DNA sequences which encode products that have nothing in common with MLK4. Therefore, some additional information with regards to structural requirements of probes, besides a **single species**

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(SEQ ID NO:1) is required, which is currently lacking in the specification. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by Bennett et al. (Geneseq Database, Accession No. AAT03098, Feb 1996). Bennett teaches a DNA sequence that has 43.9% identity to SEQ ID NO:1 and can be considered to be "homologous" to said sequence, prior to this invention.

Allowable Subject Matter

Claims 1-2, are allowed. This is because an isolated DNA molecule comprising a sequence capable of encoding SEQ ID NO:2 is free of prior art. Further the prior art does not teach or

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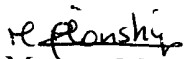
suggest preparing such specifically claimed DNA sequences. Hence said sequences are also non-obvious.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Maryam Monshipouri, Ph.D. whose telephone number is (703) 308- 1083.

The Examiner can normally be reached daily from 8:30 A.M. to 5:00 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. P. Achutamurthy, can be reached at (703) 308-3804. The OFFICIAL fax number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.


Maryam Monshipouri, Ph.D.

Primary Examiner